

JUN 29 2000

K001031

Attachment

510(k) Summary:

The Uranus, Q-Switched, Frequency Doubled NdYAG laser system is specially designed to minimize accidental exposure to hazardous radiation. The fundamental wavelength is 1064 nm. This wavelength is also frequency doubled to the shorter 532 nm green wavelength.

The Laser Max Medical Technologies Corporation user information is in compliance with section 1040.10 of CFR Chapter I, Subchapter J concerning Radiological Health published by the US Department of Health and Human Services, Center for Devices and Radiological Health, 1988.

Regarding to the 1. Burn hazard, 2. Direct eye exposure and reflection hazard 3. Safety Eyewear, 5. Operating room and patient safety 6. Using the proper power receptacle and plug, 7. Fire hazard and explosion, 8. High voltage hazard, 9. Fuse replacement, 10. Grounding the unit, 11. International standards compliance, 12. Training requirements, 13. Indications for use, 14. Precaution, 15. Warnings, 16. Contraindications, 17. Complication/Adverse effects and 18. Labeling are discussed in the Chapter one of the Uranus Instruction Manual.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 29 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Paul Y. Fang, M.D., Ph.D.
Regulatory Affairs Director
Laser Max Medical Technologies Corp.
1601 North Clancy Street
Visalia, California 93291

Re: K001031
Trade Name: Uranus, Comfortouch Laser System
Regulatory Class: II
Product Code: GEX
Dated: May 29, 2000
Received: May 31, 2000

Dear Dr. Fang:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Paul Y. Fang, M.D., Ph.D.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.

Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

April 13, 2000

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ADDITIONAL AMENDMENT

510 (k) NUMBER (if known): K 001031

DEVICE NAME: Uranus, Comfortouch Laser System

1. INDICATIONS FOR USE

The Uranus Comfortouch Laser System at 1064 nm wavelength is intended for dark ink removal. The 532 nm wavelength is intended for removal of light ink tattoos, and the lightening of vascular lesions and pigmented lesions. Type of vascular lesions include port wine birthmarks, telangiectasias, spider angiomas, cherry angiomas, and spider nevi. Types of benign epidermal pigmented lesions include café au lait birthmarks, solar lentigines, senile lentigines, Becker's nevi, freckles, and nevus spilus.


PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use YES
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 001031